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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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1. 343,337 11-02-98 BURCHELL B MUR-7450

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11/02/1210

EXAMINER

TAYLOR, J

ART UNIT	PAPER NUMBER
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1655

16

DATE MAILED:

12/18/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/142,095

Applicant(s)

BURCHELL, BRIAN

Examiner

Janell Taylor Cleveland

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 1-13 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

There is no claim 9. Misnumbered claims 10-14 have been renumbered 9-13 are are referred to as such in the remainder of this office action.

2. Claim 13 is objected to because the claim recites specific sequences, however no corresponding SEQ ID NOS are given correlating to the sequences. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In Ex parte Forman, 230 USPQ 546 (Bd. App. 1986), the Board considered the issue of enablement in molecular biology. In considering these factors: (a) in order to

practice the invention, the practitioner must be able to conduct a method to improve the efficacy of drug trials by screening individuals for Gilbert's Syndrome; (b) the specification provides guidance for detecting a genetic mutation which is linked with Gilbert's Syndrome; (c) working examples are presented for extracting a sample from a patient, extracting DNA, performing PCR, and then performing sequencing; (d) the invention is directed to a method for identifying a particular genetic mutation known to be related to Gilbert's Syndrome, not for improving the efficacy of drug trials; (e) the prior art teaches the detection of the mutation which is linked with Gilbert's Syndrome; (f) the level of skill in molecular biology is high; (g) the results of experiments involving screening for a drug or the efficacy of a drug trial is not predictable; (h) the claims are broadly drawn, reciting any possible method for carrying out a drug trial. Based on the above analysis, one of ordinary skill in the art would be subject to undue experimentation in improving the efficacy of drug trials.

Summary

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph. The following art was made of record in Applicant's IDS: Bosma et al. (N. Eng. J. Med., Vol. 333, No. 18, November 1995) In the event that the claims are amended to recite generally that the genetic mutation associated with Gilbert's Syndrome is assayed for, they will be anticipated by this art. Claim 13, however, which recites specific sequences, was not found in the prior art. The rest of the claims, as they now stand, are drawn to a test for detecting the genetic basis for Gilbert's syndrome in a method to improve the efficacy of drug trials, the method comprising screening samples from potential participants for the

basis of Gilbert's Syndrome and eliminating or including potential participants in a drug trial in the knowledge of them possessing or not possessing the genetic basis of Gilbert's Syndrome. They are also drawn to isolating DNA from each sample, amplifying the DNA inner region indicating the genetic basis of Gilbert's Syndrome, and identifying individuals having the genetic basis of Gilbert's Syndrome. Claims are also drawn to the genetic basis of Gilbert's Syndrome being the gene encoding UDP-glucuronosyltransferase (UGT). Claims are also drawn to the region being an upstream promoter region of the UGT1*1, and to the region to be amplified being between the -35 and -55 nucleotide region. Claim 12 is drawn to a kit containing primers.

Bosma et al teach the genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's Syndrome. They teach that "We sequenced the coding region and promoter regions of the gene for bilirubin UDP-glucuronosyltransferase-1...the only enzyme that contributes substantially to bilirubin glucuronidation- in 10 unrelated patients with Gilbert's Syndrome...The coding region of the gene for the enzyme was normal in the 10 patients with Gilbert's Syndrome. These patients were homozygous for two extra bases (TA) in the TATAA element of the 5' promoter region of the gene A(TA)TAA...The presence of the longer TATAA element resulted in the reduced expression of a reporter gene..." (Abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

December 14, 2000


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600